DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 13 2001

WARNING LETTER

VIA FEDERAL EXPRESS

Ref: OC:I1-1907
WEAC Sample 140782
Sample 140780

Mr. Oliver Su
Engineer
Importer and U.S. Agent
Compliance Certification Services
561F Monterey Road
Morgan Hill, California 95037-9001

Mr. Li Zhang
Manager
Qingdao Haier Microwave Production Co., Ltd.
Haier Industry Park, Qingdao Development District
Qingdao Shangdong 266510 CHINA

Dear Mr. Su and Mr. Zhang:

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), has recently completed its review of the analytical reports submitted by Winchester Engineering and Analytical Center (WEAC) on laboratory compliance testing of two samples of microwave ovens manufactured by Qingdao Haier Microwave Production Co., Ltd. Both samples were identified as Haier brand, one as Model MS271EWFAN and the other as Model MS171EWAAN. The microwave ovens were loaned to WEAC for comprehensive laboratory analysis of compliance with the United States (U.S.) Federal Performance Standard for Microwave Ovens, 21 Code of Federal Regulations (CFR) 1030.10. Copies of the analytical reports are enclosed for your information.

Our review of the test results found that the microwave ovens manufactured by your firm do not comply with the standard and, therefore, are in violation of section 538 of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C – Electronic Product Radiation Control, and Title 21 of the Code of Federal Regulations (CFR) 1030.10.

CDRH has determined that all products in both MS271EWFAN and MS171EWAAN model families and any other similarly designed microwave ovens fail to comply with the Federal Performance Standard for Microwave Ovens, 21 CFR 1030.10, and associated regulations as follows:

Model MS271EWFAN (WEAC sample number 140782)

1. 21 CFR 1030.10(c)(2)(v) and (c)(3)(iv) – The oven failed to comply with the requirements that the secondary safety interlock prevent microwave emission in excess of 5 mW/cm^2. The WEAC analyst reported that the maximum microwave emission level was 6.0 mW/cm^2 with just the secondary interlock operating and the door pulled out until the point of interlock actuation. A separate verification check by another analyst reported that the maximum microwave emission level was 9.5 mW/cm^2. The Federal Performance Standard, 21 CFR 1030.10(c)(3)(iv), states that the "measurements shall be made with the door fully closed as well as with the door fixed in any other position which allows the oven to operate."

2. 21 CFR 1030.10(c)(1), (c)(2)(v) and (c)(3)(iv) – The oven failed to comply with the requirements that the primary safety interlock prevent microwave emission in excess of 1 mW/cm^2. When the oven was tested with just the primary safety interlock operating and the door pulled, the microwave emission levels ranged up to 2.4 mW/cm^2. A separate verification check by another analyst reported that the microwave emission levels ranged up to 3.5 mW/cm^2.

3. 21 CFR 1030.10(c)(1), (c)(3)(ii), and (c)(3)(iv) – Since the oven was sent directly from the factory, we find that the manufacturer failed to adequately test the oven to meet the 1.0 mW/cm^2 leakage limit requirement taking into account measurement uncertainties as specified under section (c)(3)(ii). When the oven was tested with all of the safety interlocks operating and the door pulled, the microwave emission levels ranged up to 1.8 mW/cm^2. A separate verification check by another analyst reported that the microwave emission levels ranged up to 3.5 mW/cm^2.

4. 21 CFR 1030.10(c)(6)(i) - The user precaution label on the side of the door had the precautions out of order. The required precaution (b) was listed at the end as precaution (d) and the precaution listed as (b) on the label is an added precaution. All of the words must be exactly the same as stated in the standard. The required wording cannot be changed or substituted because it is specified by the standard. Any additional precaution statement should be listed at the end.

5. 21 CFR 1030.10(c)(6)(ii) – The service caution label had missing and misspelled words. The word "PROCEDUERS" should be "Manual for Proper Service Procedures ...." The words "FOR MICROWAVE OVENS AND FOR" should have been in between 'PERFORMANCE STANDARD" and "PRECAUTIONS TO BE TAKEN." The wording must be exactly as specified in the standard.

6. 21 CFR 1030.10(c)(4)(iii) – The user manual contained many incorrect wordings in the "PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY." Please refer to the analytical report for the incorrect wordings found. All of the words must be exactly the same as stated in the standard. The required wording cannot be changed or substituted because it is specified by the standard.

7. 21 CFR 1030.10(c)(5)(iii) – The service manual contained many incorrect wordings in the "PRECAUTIONS TO BE OBSERVED BEFORE AND DURING SERVICING TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY." Please refer to the analytical report for the incorrect wordings found. All of the words must be exactly the same as stated in the standard. The required wording cannot be changed or substituted because it is specified by the standard.

8. 21 CFR 1030.10(c)(2)(v) - The words "primary interlock switch" and the "secondary interlock switch" were not clearly printed in the schematic in the service manual. They were difficult to read.

Model MS71EWAAN (WEAC sample number 140780)

1. 21 CFR 1030.10(c)(2)(iv) – It was possible for the analysts to insert a straight wire into the oven cavity while the door was closed. Such an inserted wire would be expected to cause the oven to leak microwave radiation greater than 5.0 mW/cm^2. The WEAC analysts were able to insert a 0.889 mm diameter wire (0.035 inch) at the lower right corner of the door. The oven design lacks a protruding lip to prevent such insertion.

2. 21 CFR 1030.10(c)(6)(ii) – The service caution label was not permanently attached and had missing and misspelled words. The word "PROCEDUERS" should be "Manual for Proper Service Procedures…" The words "FOR MICROWAVE OVENS AND FOR" should have been in between 'PERFORMANCE STANDARD" and "PRECAUTIONS TO BE TAKEN." Please refer to the analytical report for the incorrect wordings found. All of the words must be exactly the same as stated in the standard. The required wording cannot be changed or substituted because it is specified by the standard.

3. 21 CFR 1030.10(c)(4)(iii) – The user manual contained many incorrect wordings in the "PRECAUTIONS TO AVOID POSSIBLE EXPOSURE TO EXCESSIVE MICROWAVE ENERGY." Please refer to the analytical report for the incorrect wordings found. All of the words must be exactly the same as stated in the standard. The required wording cannot be changed or substituted because it is specified by the regulations. The WEAC analyst also found that the printing was almost illegible.

4. 21 CFR 1010.3 – The date of manufacture was misspelled as "Noverber". The correct spelling should be "November."

Section 538(a)(1) and (a)(5) of the Act, Chapter V, Subchapter C prohibits any manufacturer from certifying or introducing into U.S. commerce microwave ovens which do not comply with the standard, or from failing to issue certification when there is an applicable standard. Section 538(a)(4) also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered a violation of 538(a)(4) of the Act. Under the Act, an importer is also considered to be a manufacturer (Section 531(3)).

The FDA is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include automatic detention of imported products, injunction, and/or imposition of civil penalties as provided for in Section 536 and 539 of the Act. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the factory and introduced into to U. S. commerce for the past 5 years. Provide copies of invoices and lists of applicable serial numbers with dates of shipments. In addition, if the product distribution was confined to specific geographical areas of the U.S., please specify those areas.

1. Refutation – You may submit your views and evidence to establish that the alleged failures to comply do not exist.

2. Exemption Request – You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action – If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

a. Notification Letter – Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

b. Corrective Action Plan – Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

A copy of this letter will be posted on the FDA's world wide web home page at:

http://www.fda.gov/foi/warning.htm

In your response, please reference this letter and our case number I1-1907. Mail it to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance (HFZ-342)
Division of Enforcement III
2098 Gaither Road
Rockville, Maryland 20850

This office noted that you have not responded to our report review letters, one dated June 27, 2001, (product report), and the other one dated September 12, 2001, (quality control report) (copies enclosed). You must answer those letters in addition to this Warning Letter. For this reason, Qingdao Haier Microwave Production Co., Ltd. is being placed on the import detention list and its products will be automatically detained at port of entry pending satisfactory responses to the Warning Letter and the two CDRH letters. CDRH will advise you whether your responses are satisfactory and when your firm can resume shipment to U.S. commerce.

If you have further questions on these requirements, please contact Mr. George W. Kraus, Jr. of the Electronic Products Branch at 301-594-4654, or by facsimile at 301-594-4672, or by electronic mail: gwk@cdrh.fda.gov

Sincerely yours,

Gladys Rodus

for Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosures:

Copies of WEAC Test Results – Sample Numbers 140780 and 140782
Copies of CDRH letters dated June 27, 2001, and September 12, 2001